REMARKS

Claims 39-64 are currently pending. In the interest of expediting examination of the claims, claims 23-26, 28-36, and 38 have been canceled and new claims 39-64 have been added. New claims 39-64 consolidate the subject matter of the canceled claims, as discussed in more detail below. New claims 39-64 do not constitute new matter.

The Examiner has rejected claims 14-21, 23-26, 28-36, and 33 under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner has rejected claims 32 and 33 under 35 U.S.C. § 112, first paragraph, as lacking support in the written description. The Examiner has rejected claims 14-21, 23-26, 28-36, and 38 under 35 U.S.C. § 112, first paragraph, as lacking support in the written description.

For the reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

The Claims Are Enabled

The Examiner has rejected claims 14-21, 23-26, 28-36, and 33 under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner states that it "is unclear how unrelated and terminally differentiated cell types such as red cells or stromal cells can be cultured into mature DLCs.... it is most likely that only monocytes found in the mouse bone marrow [are] actually cultured into mature DLCs."

Applicants note that claims 23-26, 28-36, and 38 have been canceled and new claims 39-64 have been added. Claims 39-51 are drawn to culturing peripheral blood monocytes and claims 52-64 are drawn to culturing bone marrow cells. Support for these amendments can be found in the specification at, for example, pages 3-4, 7-9, and the claims as originally filed. New

claims 39 and 52 also now recite that the DLC show "reactivity to anti-CD1a, anti-CD80, and anti-CD83 monoclonal antibodies." Support for this limitation can be found in the specification at, for example, page 8. New claim 52 also recites that a "subpopulation of the culture differentiates into dendritic Langerhans cells. Support for this limitation can be found in the specification at, for example, page 8-9 and Figure 3A.

Applicants submit that the claims, as amended, are enabled by the specification. Claims 39-51 are drawn to the production of dendritic Langerhans Cells (DLC) which are cultured from peripheral blood monocytes. The specification describes, as acknowledged by the Examiner, that peripheral blood monocytes are capable of differentiating into DLC. See the specification at, for example, page 1. As such, a person of ordinary skill in the art would be capable of generating DLC from peripheral blood monocytes utilizing the presently claimed method.

Further, Applicants submit that new claims 52-64, which are drawn the production of DLC which are cultured from a preparation of bone marrow cells, are enabled by the specification. The specification clearly recites culturing bone marrow cells. See the specification at, for example, pages 7-9, in particular, at Example 4. Applicants note that neither the claims nor the specification disclose that the bone marrow cells are purified such that only one cell type found in the bone marrow is utilized. The specification and claims merely recite the use of "bone marrow cells," without any qualifiers or other limitations to indicate that the bone marrow cells are purified or otherwise treated such that only one type of cell is present. Applicants assert that a person of ordinary skill in the art would understand that the plain meaning of "bone marrow cells," without any other qualifiers or identifiers, refers to a whole, unfractionated preparation of bone marrow cells in which multiple cell types are present. See MPEP § 2111.01 ("[T]he claims must be interpreted as broadly as their terms reasonably

allow.... the words of the claim must be given their plain meaning."). Furthermore, as noted above, claim 52 recites that "subpopulation of the culture differentiates into dendritic Langerhans cells," which indicates that not all of the bone marrow cells will differentiate DLC. Therefore, Applicants submit that a person of ordinary skill in the art would understand that multiple cell types are present in the "bone marrow cells" utilized in the present invention, and that such a preparation of cells would be capable of giving rise to DLC. Furthermore, a person of ordinary skill in the art would understand that not all of the cells present in the preparation of bone marrow cells will differentiate into DLC, and that only a subpopulation of the cells will do so. Accordingly, Applicants assert that production of DLC from bone marrow cells is fully enabled by the specification, based upon the plain meaning of "bone marrow cells."

The Examiner further argues that there is no evidence that the claimed methods actually result in mature DLC. Applicants submit that the claims, as amended, are enabled for the production of mature DLC. The Examiner states that "cell types are routinely identified and characterized by the cell surface markers they express." Applicants acknowledge this practice, but submit that it is not necessary to determine the expression of all known DLC markers to reasonably conclude that the cultured cells are DLC. As noted above, the pending claims recite that the DLC show "reactivity to anti-CD1a, anti-CD80, and anti-CD83 monoclonal antibodies." CD1a, CD80, and CD83 are known markers of DLC. See the specification at, for example, page 8. The cultured cells of the present invention are analyzed for the presence of dendritic morphology and processes, in addition to being analyzed for these markers. See the specification at, for example, pages 7-8. Thus, the claims, as amended, require that the resulting DLC possess dendritic morphology and processes, and are reactive to antibodies specific for CD1a, CD80, and CD83. Applicants assert that a person of ordinary skill in the art would be able to reasonably

conclude that the cultured cells which satisfy all of the criteria specified in the present claims are DLC, based on the presence of known DLC markers and the presence of morphology indicative of DLC. Accordingly, Applicants submit that the production of DLC is fully enabled by the specification.

Based upon the foregoing, Applicants submit that the claims are enabled, and respectfully request withdrawal of the rejections.

The Claims Are Supported By The Specification

The Examiner has rejected claims 32 and 33 under 35 U.S.C. § 112, first paragraph, as lacking support in the written description. The Examiner states that the cited support for step (d) of the claims "discloses only a single experiment employing only human monocytes incubated in serum free medium with autologous platelets" but does not support a generic method. The Examiner has rejected claims 14-21, 23-26, 28-36, and 38 based upon the same grounds

As noted above, claims 39-51 are drawn to culturing peripheral blood monocytes, and claims 52-64 have been added which are drawn to culturing bone marrow cells. Applicants assert that the claims, as amended, satisfy the written description requirement because the specification discloses the use of both mouse and human peripheral blood monocytes, as well as the use of bone marrow cells. See the specification at, for example, pages 7-9. The specification further recites that the method may be utilized with any mammalian species, provided that the cells are derived from the "same species or phylogenetically close species." *Id.* at page 9. Applicants submit that this disclosure is sufficient to describe the genus as presently claimed, because the specification discloses a common structure sufficient to satisfy the written description requirement, *e.g.*, it specifies that the cells are derived from the "same species or

phylogenetically close species." See MPEP § 2163. A person of ordinary skill in the art would understand that the inventors would be capable of culturing cells from the same species or phylogenetically close species at the time of filing, and therefore, would understand that the inventors had possession of the claimed genus. Accordingly, Applicants submit that the claims are fully supported by the specification.

Applicants note that claim 50 recites that the peripheral blood monocytes and the platelets are human. As acknowledged by the Examiner, the specification at pages 7-9 disclose the use of human monocytes incubated with autologous platelets. While the present claims do not recite the use of serum-free medium, the use of such medium was well known in the art at the time of filing, and need not be explicitly recited. MPEP § 2163.

The Examiner also states that there is insufficient support for the limitation "approximately 20%," and that the claim should recite "only approximately 20%." Applicants note that the limitation "approximately 20%" has been deleted from the claims. Support for this amendment can be found in the specification at, for example, pages 8, and the claims as originally filed. Accordingly, the Examiner's rejection with regard to this limitation has been rendered moot.

The Examiner has rejected claims 14-21, 23-26, 28-36, and 38 under 35 U.S.C. § 112, first paragraph, as lacking support in the written description. The Examiner states that there is insufficient support for the term "monitoring."

Applicants note that the new claims now recite "analyzing" the cultured cells instead of "monitoring" the cultured cells. Support for these amendments can be found in the specification at, for example, pages 7-8. The specification clearly discloses that the cultured cells are "analysed [sic] under phase contrast microscope" for the presence of dendritic processes. *Id.*; see

also, for example, Figure 1D. The specification also discloses that the cultured cells are immunophenotyped via flow cytometry for markers associated with DLC. See the specification at, for example, pages 7-8. Based upon these disclosures, a person of ordinary skill in the art would understand that the term "analyzing" encompasses the various methods disclosed in the specification for the detection of dendritic processes and markers, and that such methods could be performed on many types of cells under various culture conditions. Accordingly, Applicants submit that the recitation of the term "analyzing" in the claims is fully supported by the specification.

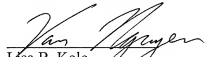
The Examiner also states that there is insufficient support for the use of rat monocytes. Applicants note that the present claims do not recite the use of rat monocytes. Support for this amendment can be found in the specification at, for example, pages 7-9. Applicants submit that these amendment address the issues raised by the Examiner.

Based upon the foregoing, Applicants submit that the claims are supported by the written description, and respectfully request withdrawal of the rejections.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Applicants believe that the inventions described and defined by claims 39-64 are patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claims is requested.

Respectfully submitted,



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